OPA DATABASE GUIDE

FOR

PUBLIC USERS - MANUFACTURERS

JULY 2011
VERSION 1.0

Prepared by:
Primescape Solutions, Inc.
PRIMESCAPE
We Deliver Solutions

CONTENTS

Manufacturers 1
- Manufacturers 1
- Registering a Manufacturer 2
- Search Manufacturers 4
- Advanced Search Options 4
- Searching for Manufacturers 5
- Search Results 5
- Export Results 6
- Viewing Manufacturer 7

MANUFACTURERS

Objectives:

- Searching for a Manufacturer
- Registering a Manufacturer

MANUFACTURERS

DETAILS	EXAMPLE

Manufacturers

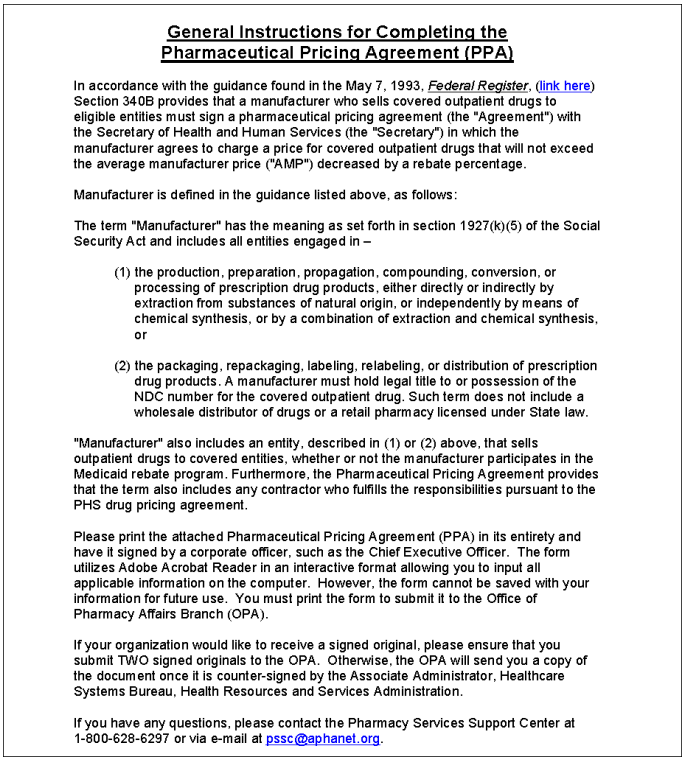
- The Manufacturers menu provides two links: 1) Search Manufacturers and 2) Register a Manufacturer.
- Navigate to links from the toolbar and the Manufacturers menu displays the links or from the Manufacturers section.

MANUFACTURERS	
DETAILS	**EXAMPLE**

Registering a Manufacturer

- Registering a Manufacturer form is in .pdf format and requires Adobe reader.
- Registering a Manufacturer requires the Manufacturer to be in compliance and agreement with the *Pharmaceutical Pricing Agreement (PPA).*
- Email notifications are generated to the contacts, once OPA has reviewed and approved.

1. Click on Register a Manufacturer link.
2. Print the document and carefully review the instructions and detailed agreement.



General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:

The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

(1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the Pharmacy Services Support Center at 1-800-628-6297 or via e-mail at pssc@aphanet.org.

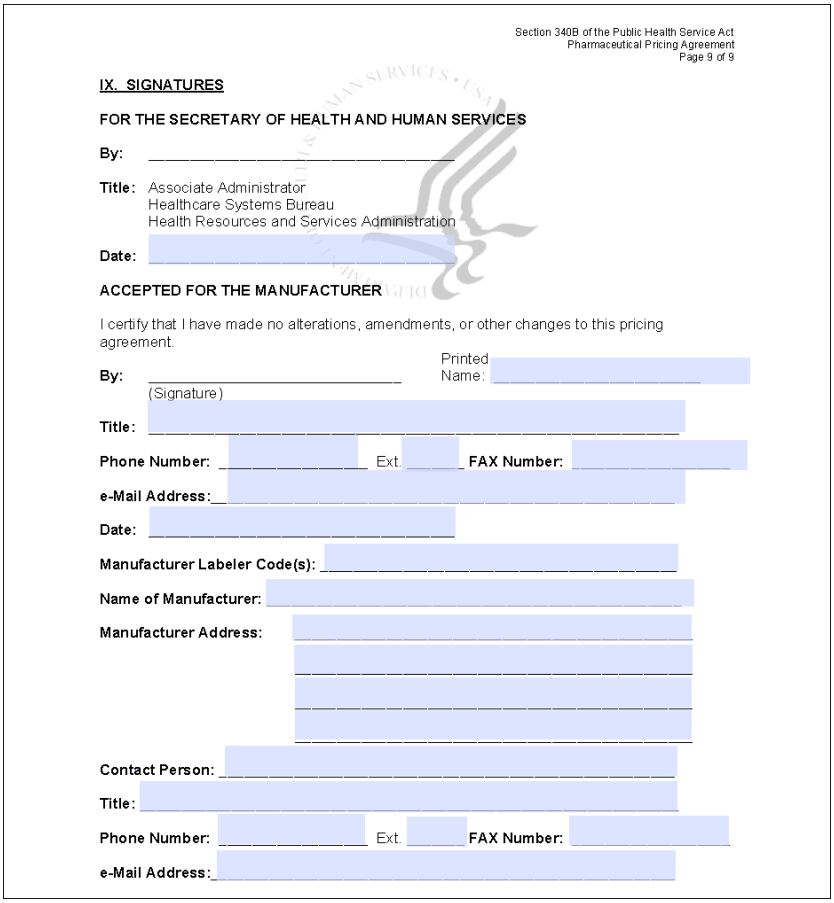
MANUFACTURERS	
DETAILS	**EXAMPLE**

3. Using a computer, enter all applicable information on the last page of the Pharmaceutical Pricing Agreement, which includes contact information and signatures.

The document cannot be completed, saved, and submitted for future use. Complete the document and print out. .

4. Submit the original printed form to the Office of Pharmacy Affairs Branch (OPA).

If you want a signed original for your records, submit two signed copies to OPA.



Section 340B of the Public Health Service Act
Pharmaceutical Pricing Agreement
Page 9 of 9

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: _____
(Signature)

Title: _____

Phone Number: _____ Ext. _____ FAX Number: _____

e-Mail Address: _____

Date: _____

Manufacturer Labeler Code(s): _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

_____

_____

Contact Person: _____

Title: _____

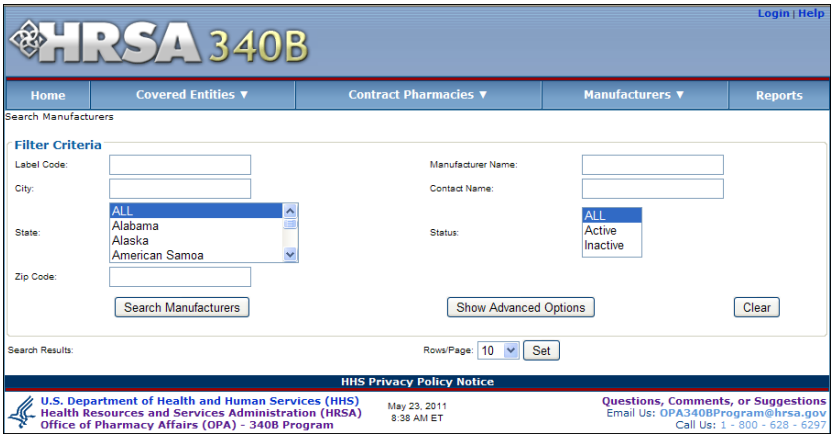
Phone Number: _____ Ext. _____ FAX Number: _____

e-Mail Address: _____

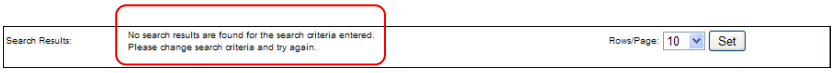
MANUFACTURERS	
DETAILS	**EXAMPLE**

Search Manufacturers

- The Search Manufacturers screen provides navigation to select and view Manufacturer records, export data for reports, and create data export spreadsheets.
- The more criteria entered, the more filtered the Results.
- Each Label Code links to a Manufacturer Detail record.



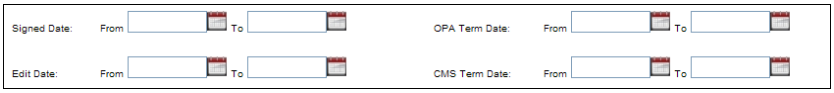
- A message displays if no results are found based on the search criteria entered.



Advanced Search Options

Advanced Search Option provides advanced query options for specific criteria, which is an option.

- Show Advanced Options provides Four date range searches for: Signed Date, Edit Date, OPA Termination Date, and CMS Termination Date.
- Required to include a From and To date range.
- Hide Advanced Options button removes the Advanced Options from view.
- Clear button clears information entered.

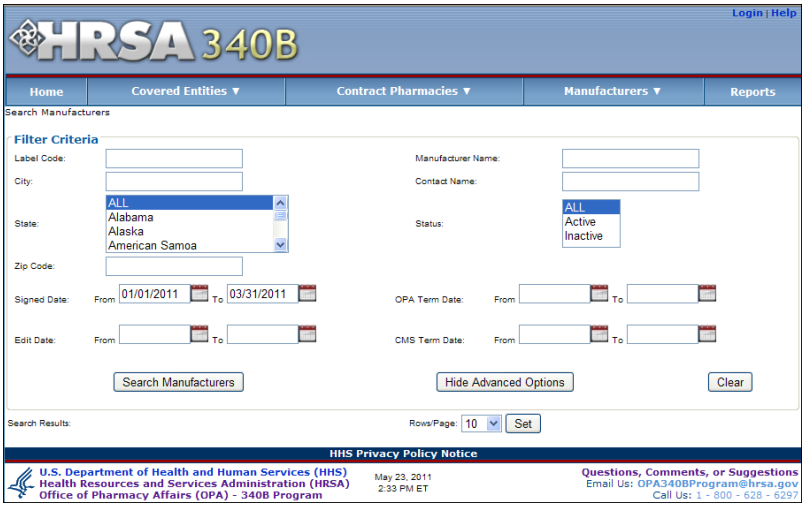


MANUFACTURERS

DETAILS	EXAMPLE

Searching for Manufacturers

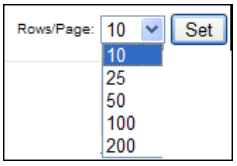
1. Click the Show Advanced Options button to expand search.
2. Enter applicable search criteria.
3. Click the Search Manufacturers button and the Manufacturers Results table displays.



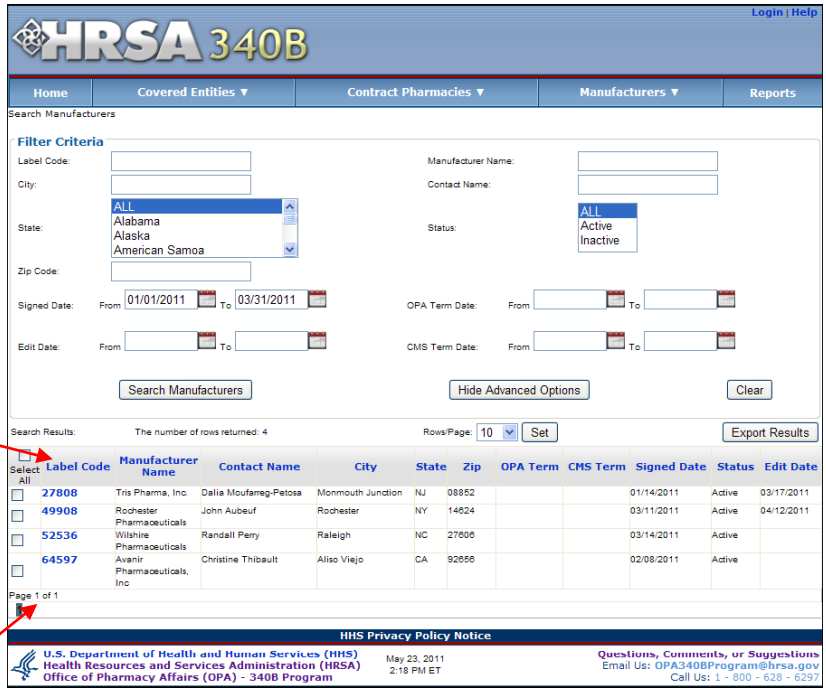
Search Results

The Search Results displays in uniform table format.

- Number of rows display default is 10, can be set be to 10 to 200 rows.



- Columns are sortable. Click the column heading to change sort to descending order. The default is by ascending order.
- Select All checkbox selects all records in the Search Results table.
- Click a Label Code (i.e., 49908) which links to the Manufacturer Detail record.
- Lists number of pages at the bottom, which changes if the number of rows is changed. Click on the next number to move to view the next group of records.



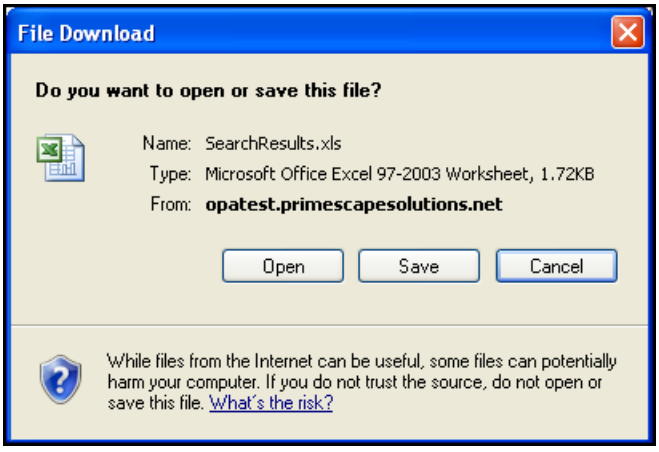
MANUFACTURERS	
DETAILS	**EXAMPLE**

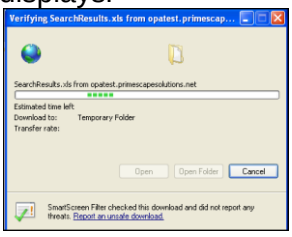
Export Results

- To export data for specific Manufacturer records initiates from a Manufacturer Search.

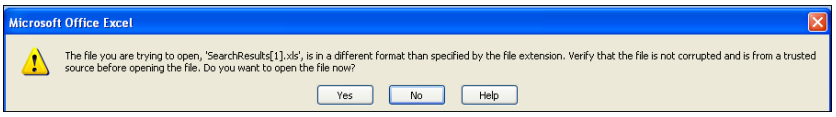
1. Enter search criteria and Search Results table displays.
2. Click on checkbox(es) for applicable Manufacturer record(s).
3. Click the Export Results button and the File Download screen displays.

4. Select Open button to open file, or Save button to save file.
5. Verify Search Results window displays.

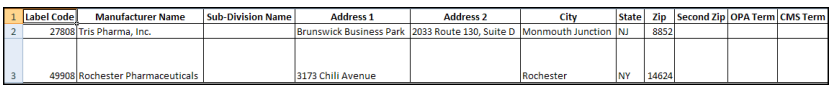




6. Click the Yes button to and the Excel spreadsheet displays. Or, Click the No button to cancel.



- Excel spreadsheet displays. This is a partial view.



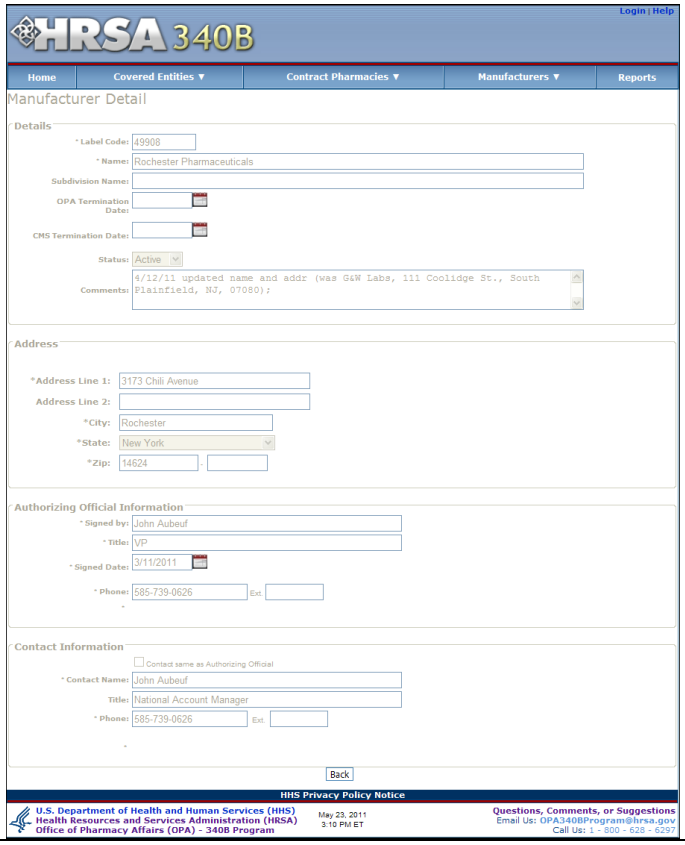
	Label Code	Manufacturer Name	Sub-Division Name	Address 1	Address 2	City	State	Zip	Second Zip	OPA Term	CMS Term
2	27808	Tris Pharma, Inc.		Brunswick Business Park	2033 Route 130, Suite D	Monmouth Junction	NJ	8852			
3	49908	Rochester Pharmaceuticals		3173 Chili Avenue		Rochester	NY	14624			

MANUFACTURERS

DETAILS	EXAMPLE

Viewing Manufacturer

Manufacturer records can be accessed for viewing using the Search screen.

- Manufacturer Detail records available for view:
  - Approved
  - Approved with a future start date
  - Terminated
  - Terminated with a future start date
- Manufacturers that have not been approved, are not viewable.
- Covered Entity Detail screen displays as view only; edits cannot be made.

1. Conduct search.
2. Click the Search Manufacturers button and Search Results displays.
3. Select applicable Label Code and Manufacturer Detail record displays.
4. Click the Back button and the Search Manufacturers screen displays.